

JFw

DOCKET NO.: P0453.70113US03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent & Trademark Office  
O I P E S E R I E S  
AUG 09 2004

Applicant: Foss et al.  
Serial No.: 10/785,320  
Confirmation No.: 1614  
Filed: February 24, 2004  
For: ORAL USE OF METHYLNALTREXONE AND RELATED  
COMPOUNDS TO INDUCE LAXATION IN CHRONIC OPIOID  
USERS

Examiner: Not Yet Assigned  
Art Unit: 1614

---

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 6 day of August, 2004.

*Kristin J. Ketelhut*  
Kristin J. Ketelhut

---

MAIL STOP AMENDMENT  
Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

Information Disclosure Statement  
 PTO Form 1449 with cited references  
 Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
*Foss et al., Applicant*

By: *Edward R. Gates*  
Edward R. Gates, Reg. No. 31,616  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2211  
Telephone: (617)646-8000

Docket No. P0453.70113US03  
Date: August 6, 2004  
xNDDx



DOCKET NO: P0453.70113US03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Foss et al.  
Serial No: 10/785,320  
Confirmation No: 1614  
Filed: February 24, 2004  
For: ORAL USE OF METHYLNALTREXONE AND RELATED  
COMPOUNDS TO INDUCE LAXATION IN CHRONIC  
OPIOID USERS  
Examiner: Not Yet Assigned  
Art Unit: 1614

---

**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 6 day of August, 2004.

*Kristin J. Ketelhut*  
Kristin J. Ketelhut

---

**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF**  
**DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**PART I: Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

**PART II: Information Cited**

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
P0453.70110US01	10/779,129	February 12, 2004	Foss et al.
P0453.70112US01	10/821,813	April 8, 2004	Boyd et al.
P0453.70113US00	10/357,669	February 4, 2003	Foss et al.
<sup>1</sup> P0453.70113US01	10/779,128	February 12, 2004	Foss et al.
<sup>1</sup> P0453.70113US03	10/785,320	February 12, 2004	Foss et al.
<sup>1</sup> P0453.70113US04	10/785,668	February 24, 2004	Foss et al.
P0453.70115US01	10/821,811	April 8, 2004	Sanghvi et al.
P0453.70116US01	10/821,809	April 8, 2004	Sanghvi et al.

<sup>1</sup>Copy not enclosed; see P0453.70113US00, Serial No. 10/357,669 for identical specification

The following are remarks concerning the other information cited:

**PART III: Remarks**

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
Foss et al., *Applicant*

By: Edward R. Gates  
Edward R. Gates, Reg. No. 31,616  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2211  
Telephone: (617) 646-8000

Docket No. P0453.70113US03

Date: August 6, 2004

**XNDDX**

AUG 09 2004

FORM PTO-1449/A and B (Modified)

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

Sheet 1 of 3

APPLICATION NO.:	10/785,320	ATTY. DOCKET NO.:	P0453.70113US03
FILING DATE:	February 24, 2004	CONFIRMATION NO.:	1614
APPLICANT:	Foss et al.		
GROUP ART UNIT:	1614	EXAMINER:	Not Yet Assigned

## U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A30	4,311,833		Namikoshi, et al.	01-19-1982
	A31	4,377,568		Chopra, et al.	03-22-1983
	A32	4,385,078		Onda, et al.	05-24-1983
	A33	4,457,907		Porter, et al.	07-03-1984
	A34	4,462,839		McGinley, et al.	07-31-1984
	A35	4,518,433		McGinley, et al.	05-21-1985
	A36	4,556,552		Porter, et al.	12-03-1985
	A37	4,606,909		Bechgaard, et al.	08-19-1986
	A38	4,615,885		Nakagame, et al.	10-07-1986
	A39	4,670,287		Tsuji, et al.	06-02-1987
	A40	4,857,833		Sherman, et al.	08-15-1999
	A41	4,888,346		Bihari, et al.	12-19-1989
	A42	5,426,112		Zagon, et al.	06-20-1995
	A43	5,536,507		Abramowitz, et al.	07-16-1996
	A44	5,567,423		Ying, et al.	10-22-1996
	A45	5,591,433		Michael, et al.	01-07-1997
	A46	5,597,564		Ying, et al.	01-28-1997
	A47	5,609,871		Michael, et al.	03-11-1997
	A48	5,614,222		Kaplan, et al.	03-25-1997
	A49	5,626,875		Ballester Rodes, et al.	05-06-1997
	A50	5,629,001		Michael, et al.	05-13-1997
	A51	6,025,154		Li, et al.	02-15-2000
	A52	6,353,004	B1	Farrar, et al.	03-05-2002
	A53	6,469,030	B2	Farrar, et al.	10-22-2002
	A54	2001/0036951	A1	Farrar, et al.	11-01-2001

## FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
	B22	AU	758,416		Arch Development Corp.	07-03-1999	
	B23	CA	2,312,234		Arch Development Corp.	05-14-1999	
	B24	DE	3,780,819				
	B25	EP	1,047,726	A1	Quest International B.V.	07-22-1999	
	B26	WO	99/22737	A1	Arch Development Corp.	05-14-1999	
	B27	WO	04/043964	A2	Mallinckrodt	05-27-2004	

FORM PTO-1449/A and B (Modified)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>			APPLICATION NO.: 10/785,320	ATTY. DOCKET NO.: P0453.70113US03
			FILING DATE: February 24, 2004	CONFIRMATION NO.: 1614
			APPLICANT: Foss et al.	
			GROUP ART UNIT: 1614	
Sheet	2	of	3	EXAMINER: Not Yet Assigned

**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C118	ALTIER et al., Opioid receptors in the ventral tegmental area contribute to stress-induced analgesia in the formalin test for tonic pain. <i>Brain Res.</i> 1996 Apr 29;718(1-2):203-6.	
	C119	BAKER et al., Functional effects of systemically administered agonists and antagonists of mu, delta, and kappa opioid receptor subtypes on body temperature in mice. <i>J Pharmacol Exp Ther.</i> 2002 Sep;302(3):1253-64.	
	C120	BASILISCO et al., Oral naloxone antagonizes loperamide-induced delay of orocecal transit. <i>Dig Dis Sci.</i> 1987 Aug;32(8):829-32.	
	C121	BASILISCO et al., Effect of loperamide and naloxone on mouth-to-caecum transit time evaluated by lactulose hydrogen breath test. <i>Gut.</i> 1985 Jul;26(7):700-3.	
	C122	BOWEN et al., Antagonism of the antinociceptive and discriminative stimulus effects of heroin and morphine by 3-methoxynaltrexone and naltrexone in rhesus monkeys. <i>J Pharmacol Exp Ther.</i> 2002 Jul;302(1):264-73.	
	C123	BOWEN et al., College on Problems of Drug Dependence 64th Annual Scientific Meeting, June 8-13, 2002. Quebec City, Quebec, Canada. Abstracts. <i>Drug Alcohol Depend.</i> 2002 May 1;66 Suppl 1:S1-220. Abstract No. 65.	
	C124	CARR et al., Naltrexone antagonizes the analgesic and immunosuppressive effects of morphine in mice. <i>J Pharmacol Exp Ther.</i> 1994 May;269(2):693-8.	
	C125	CHOI et al., Opioid antagonists: a review of their role in palliative care, focusing on use in opioid-related constipation. <i>J Pain Symptom Manage.</i> 2002 Jul;24(1):71-90. Review.	
	C126	CHOI et al., Inhibition of chemokine-induced chemotaxis of monkey leukocytes by mu-opioid receptor agonists. <i>In Vivo.</i> 1999 Sep-Oct;13(5):389-96.	
	C127	DE PONTI et al., Methylnaltrexone Progenics. <i>Curr Opin Investig Drugs.</i> 2002 Apr;3(4):614-20. Review.	
	C128	FLORES et al., Mechanisms of morphine-induced immunosuppression: effect of acute morphine administration on lymphocyte trafficking. <i>J Pharmacol Exp Ther.</i> 1995 Mar;272(3):1246-51.	
	C129	GILES et al., Quaternary opiate antagonists lower blood pressure and inhibit leucine-enkephalin responses. <i>Eur J Pharmacol.</i> 1983 Nov 25;95(3-4):247-52.	
	C130	HO et al., Suppression of immunological functions in morphine addicted mice. <i>NIDA Res Monogr.</i> 1986;75:599-602.	
	C131	KEHLET et al., Review of postoperative ileus. <i>Am J Surg.</i> 2001 Nov;182(5A Suppl):3S-10S. Review.	
	C132	KOSTEN et al., Naltrexone and morphine alter the discrimination and plasma levels of ethanol. <i>Behav Pharmacol.</i> 1999 Feb;10(1):1-13.	
	C133	KOSTIC, CAS Abstract Document No. 127: 13345, 1997.	
	C134	LI et al., Methadone enhances human immunodeficiency virus infection of human immune cells. <i>J Infect Dis.</i> 2002 Jan 1;185(1):118-22. Epub 2001 Dec 14.	
	C135	MACK, Paralytic ileus: response to naloxone. <i>Br J Surg.</i> 1989 Oct;76(10):1101.	
	C136	NEMETH-LEFKOWITZ et al., Research communication in Substances of Abuse (1980) 1(2): 177-83.	
	C137	PHAM et al., Drugs of Abuse: Chemistry, Pharmacology, Immunology and AIDS; National Institute of Drug Research 96: Monograph Series. U.S. Department of Health and Human Services; 1990.	
	C138	QUANG-CONTAGREL et al., Long-term methadone treatment: effect on CD4+ lymphocyte counts and HIV-1 plasma RNA level in patients with HIV infection. <i>Eur J Pain.</i> 2001;5(4):415-20.	
	C139	SAKURADA et al., Differential antagonism of endomorphin-1 and endomorphin-2 supraspinal antinociception by naloxonazine and 3-methylnaltrexone. <i>Peptides.</i> 2002 May;23(5):895-901.	
	C140	SANDNER-KEISLING et al., Pharmacology of opioid inhibition to noxious uterine cervical distension. <i>Anesthesiology.</i> 2002 Oct;97(4):966-71.	
	C141	SHAVIT et al., Effects of a single administration of morphine or footshock stress on natural killer cell cytotoxicity. <i>Brain Behav Immun.</i> 1987 Dec;1(4):318-28.	
	C142	SOLDANI et al., Central and peripheral involvement of mu receptors in gastric secretory effects of opioids in the dog. <i>Eur J Pharmacol.</i> 1985 Nov 19;117(3):295-301.	
	C143	STEINBROOK et al., An opioid antagonist for postoperative ileus. <i>N Engl J Med.</i> 2001 Sep 27;345(13):988-9.	

<b>FORM PTO-1449/A and B (Modified)</b> <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/785,320	ATTY. DOCKET NO.: P0453.70113US03
				FILING DATE: February 24, 2004	CONFIRMATION NO.: 1614
				APPLICANT: Foss et al.	
				GROUP ART UNIT: 1614	EXAMINER: Not Yet Assigned
Sheet	3	of	3		

C144	WEI et al., Abstracts of the 2002 Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics. Atlanta, Georgia, USA. March 24-27, 2002. Clin Pharmacol Ther. 2002 Feb;71(2):P1-136.		
C145	WILMORE et al., Can we minimize the effects of opioids on the bowel and still achieve adequate pain control? Am J Surg. 2001 Nov;182(5A Suppl):1S-2S.		
C146	WYBRAN et al., Suggestive evidence for receptors for morphine and methionine-enkephalin on normal human blood T lymphocytes. J Immunol. 1979 Sep;123(3):1068-70.		
C147	YUAN, Clinical Status of Methylnaltrexone, A New Agent to Prevent and Manage Opioid-Induced Side Effects. J Support Oncol. 2004 Mar/Apr; 2(2):111-22.		

EXAMINER	DATE CONSIDERED

#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_\_, filed \_\_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - The Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC 371 after June 30, 2003. See 37 CFR 1.491(b). For all patent applications filed on or before June 30, 2003, copies of cited U.S. patents and patent application publications are still required unless an eIDS is filed. Copies of all other patent(s), publication(s), or other information listed must still be provided, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]